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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/908,943	07/19/2001	Riqiang Yan	29915/00281A.US	1034

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EXAMINER

CELSA, BENNETT M

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 05/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/908,943

Applicant(s)

YAN ET AL.

Examiner

Bennett Celsa

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 January 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 102-131 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 102-131 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION: Further Restriction/Election

Status of the Claims

Claims 102-131 are currently pending.

Applicant's election of Groups 5430-8370 (methods for assaying beta-secretase modulators) and SYEV as the peptide substrate motif in the correspondence dated 1/31/05 is acknowledged.

In light of applicant's newly presented claims and upon further consideration, the following Restriction/election of species is being instituted.

NOTE: this application has been transferred to PRIMARY EXAMINER CELSA : AU 1639 (see correspondence information below).

Election/Restrictions (Lack of Unity)

This application contains claims directed to the following patentably distinct species of the claimed invention:

ASSAY MILEU (lack of unity/burdensome search):

I. In vitro assay: Claims 102-128 and 131, drawn to an *in vitro* competitive binding assay for a modulator of beta secretase activity, classified in class 435, subclass 7.1.

OR

II. In vivo assay :Claims 129 and 130, drawn to an *in vivo* (e.g. transgenic non-human mammal) competitive binding assay , classified in class 424, subclass 93.1.

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The above-cited methods of Groups I and II lack unity of invention since these inventions fail to share a "special" common technical feature since:

A polypeptide with beta secretase APP processing activity (e.g. Hu-Asp2) and a substrate (seq. 113: EVNL-DAEFR) for use in an assay are known in the art (e.g. see Specification pages 1-2) as are secretase substrates (VKM-DAEF) comprising a P2P1-P1'P2' motif comprising KMDA which is within the scope of the presently claimed invention. See Tsien et al. US Pat. No. 5,981,200 (11/99) at col. 14 (Table III) and patent claims 1-7, especially claims 1, 9, 12 etc. Additionally, the methods require different and separately burdensome manual/computer bibliographic and classification in patent and literature database due to their divergent subject matter.

Accordingly, applicant must elect either Group I. Or Group II above.

POLYPEPTIDE WITH BETA SECRETASE APP ACTIVITY (lack of unity/burdensome search):

The claimed invention encompasses beta secretase polypeptides (E.g. SEQ 2 OR 4 etc.) comprising different amino acid sequences which although sharing a common utility, nevertheless fail to share a substantial structural feature disclosed as being essential to that utility and thus lack unity of invention. See MPEP 803.02. Additionally, the bibliographic and sequence searches for the scope of secretase polypeptides (and corresponding nucleic acids) would be unduly burdensome.

Accordingly, applicant must elect a single secretase polypeptide sequence and if available a corresponding coding nucleic acid sequence and indicate claims readable thereon.

SECRETASE SUBSTRATE (species election: burdensome search):

The claim (elected) invention comprises the use of substrate peptide motifs which comprise the tetrapeptide SYEV in the presently claimed assays. However, the scope of peptides that comprise this core structure is huge since there is no limit placed on the number of amino acids and the composition of amino acids N- or C- terminal to this motif. Accordingly, the bibliographic, classification and sequence searches for the entire scope of SYEV containing peptides would be unduly burdensome.

Accordingly, applicant must elect a single peptide species (e.g. a single compound) which comprises SYEV and indicate claims readable thereon.

Applicant is advised that a reply to this requirement must include an identification of the species (e.g. milieu, secretase peptide and substrate) that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record

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showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Future Correspondences:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bennett Celsa whose telephone number is 571-272-0807. The examiner can normally be reached on 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bennett Celsa
Primary Examiner
Art Unit 1639

BC
April 21, 2005

